ATRIO HEALTH PLANS

Zynyz

Zynyz (retifanlimab-dlwr) J9345

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **500 mg IV infusion over 30 minutes every 4 weeks**

☐ **Other Regimen**_____

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Merkel Cell Carcinoma**

☐ Patient has metastatic or recurrent locally advanced disease not amenable to surgery or radiation.

☐ Patient is using Zynyz as monotherapy.

☐ Patient has not received prior treatment with an anti-PD-1 or PD-L1 agent.

☐ **dMMR/MSI-H or POLE/POLD1 Solid Tumors**

☐ Patient is using Zynyz as a single agent.

☐ Patient is using for one of the following:

- ☐ Colon Cancer; OR
- ☐ Rectal Cancer; OR
- ☐ Small Bowel Adenocarcinoma.

☐ Patient has one of the following molecular findings:

- ☐ Deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H); OR
- ☐ Polymerase epsilon/delta (*POLE/POLD1*) mutation w/ ultra-hypermutated phenotype (ex: TMB > 50 mut/Mb)

☐ Anal Carcinoma

☐ Patient has a diagnosis of anal carcinoma.

☐ Select ONE of the following treatment scenarios:

- ☐ Option A: Monotherapy (Second-line and subsequent)
  - ☐ Patient is using Zynyz as monotherapy.
  - ☐ Patient has disease progression on or after platinum-based chemotherapy.
  - ☐ Patient has locally recurrent or metastatic squamous cell carcinoma of the anal canal.
  - ☐ Patient is using it as second-line or subsequent therapy.
  - ☐ Patient has not received prior treatment with an anti-PD-1 or PD-L1 agent.
- ☐ Option B: Combination First-line Therapy
  - ☐ Patient is using Zynyz in combination with paclitaxel and carboplatin.
  - ☐ Patient is using it as first-line treatment.
  - ☐ Patient has inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal.

☐ Documentation bone marrow transplant failure / unsuitability attached.

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)

- ☐ Patient had an **adequate response** or **significant improvement** while on this medication.
- ☐ Member's MAXIMUM length of treatment is 24 months of therapy.
  (will not be approved beyond 24th month)

If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Zynyz Prior Authorization

Drug Name(s):
ZYNYZ **RETIFANLIMAB-DLWR**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:
N/A

Prescriber Restrictions:
Oncologist or other related specialist

Coverage Duration:
Approval will be for 6 months

FDA Indications:
Zynyz

- Malignant neoplasm of anal canal, Squamous cell carcinoma, inoperable locally recurrent or metastatic, first-line, in combination with carboplatin and paclitaxelView additional information.
- Malignant neoplasm of anal canal, Squamous cell carcinoma, locally recurrent or metastatic, with progression on or intolerance to platinum-based chemotherapy, as a single agentView additional information.
- Merkel cell carcinoma, Locally advanced, metastatic or recurrent

Off-Label Uses:
N/A

Age Restrictions:
Safety and effectiveness have not been established in pediatric patients

Other Clinical Consideration:
N/A

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Zynyz&UserSearchTerm=Zynyz&SearchFilter=filterNone&navitem=searchGlobal#